IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

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UNITED STATES OF AMERICA, Plaintiff, vs. UTAH MEDICAL PRODUCTS, INC., a Utah corporation; KEVIN L. CORNWELL and BEN D. SHIRLEY, individuals, Defendants.	)	Case No. 2:04-CV-733 BSJ **MEMORANDUM OPINION & ORDER**

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This matter was tried to the Court from September 26 through October 4, 2005. Arnold Allan Gordus of the Department of Justice and Claudia J. Zuckerman of the Office of Chief Counsel for the Food & Drug Administration appeared on behalf of plaintiff United States of America ("United States"). Daniel G. Jarcho, Cass W. Christensen, and Daniel L. Russell, Jr., of McKenna Long & Aldridge LLP, appeared on behalf of defendants Utah Medical Products, Inc., Kevin Cornwell and Ben Shirley (collectively "Utah Medical").

INTRODUCTION

On behalf of the Food and Drug Administration ("FDA"), the United States seeks a permanent injunction against Utah Medical under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 332(a), regarding alleged violations of the Quality System Regulation ("QSR"), 21 C.F.R. Part 820 (2004). Utah Medical is a corporation organized under the laws of Utah, with its

principal executive offices at 7043 South 300 West, Midvale, Utah 84047. Defendant Kevin L. Cornwell is the Chairman and Chief Executive Officer of Utah Medical. Mr. Cornwell is involved in the day-to-day operations of Utah Medical and has authority over all of the Company's operations, including the design, manufacture, packing and storage of Utah Medical's devices. Mr. Cornwell is ultimately responsible for Utah Medical's compliance with all applicable laws and regulations. Mr. Cornwell performs his duties at the Company's principal offices, within the jurisdiction of this Court. Defendant Ben L. Shirley is the Vice President of Quality Assurance and Product Development at Utah Medical and is involved in the day-to-day activities of Utah Medical. Mr. Shirley is also responsible for compliance with the QSR at Utah Medical's Utah facility. Mr. Shirley performs his duties at the Company's principal offices, within the jurisdiction of this Court.

Utah Medical develops, manufactures, and markets a broad range of disposable and reusable specialty medical devices. Utah Medical's current product line includes devices for labor and delivery, neonatal intensive care, gynecology, urology, electrosurgery and blood pressure monitoring. Utah Medical regularly manufactures devices from components that it receives in interstate commerce and introduces finished devices into interstate commerce. Utah Medical also manufactures "components," as defined at 21 C.F.R. § 820.3(c) (2004),[1] because it manufactures parts or subassemblies that are intended to be included as part of finished, packaged and labeled medical devices.

The two main methods by which Utah Medical manufactures its components are its

[1]"Component means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device." 21 C.F.R. 820.3(c) (2004).

extrusion process and injection molding process. "Extrusion" is a process in which plastic is extruded, or pushed, through a fixed die (or orifice) in order to assume its final shape. "Injection molding" is a process in which liquified plastic is injected into a mold cavity in order to assume its final shape. The entirety of Utah Medical's extrusion and injection molding operations are devoted to component manufacturing. No products other than components are manufactured with Utah Medical's extrusion or injection molding operations.

Utah Medical sells the large majority of the components it manufactures to other entities, including its wholly-owned subsidiary in Ireland (Utah Medical Products, Ltd.), to be used by these other entities in the manufacture of finished products.[2] For example, in 2004, Utah Medical manufactured a total of 29,549,139 units of injection-molded or extruded components. In the same year, Utah Medical sold approximately 73% of these molded or extruded components to other entities, to be used by the other entities in the manufacture of finished products. In the case of the Irish subsidiary, the manufacture of finished medical device products (and the use of those products) occurs solely outside of the United States.[3] Some of the companies that purchase components manufactured by Utah Medical do not manufacture medical devices.[4]

Utah Medical asserts that it has a comprehensive quality system, intended to comply with all Quality System Regulations provisions. As part of its quality system, Utah Medical has

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[2]Because the burden of ensuring the quality of components rests upon the finished device manufacturer (*see* 21 C.F.R. 820.80), the QSR does not regulate Utah Medical's components to be sold to manufacturers of finished products.

[3]The QSR does not regulate devices made and distributed outside of the United States. *See* 21 C.F.R. 820.1(a)(2).

[4]But here, the United States' case focuses on the production of plastic components that are incorporated in medical devices.

implemented a broad range of protocols, policies, and procedures to design, produce, test, and distribute quality components and medical devices. The FDA has inspected Utah Medical several times since 2001. During certain inspections, the FDA has issued written observations by FDA inspectors on Forms FDA-483. A Form FDA-483 is a list of concerns observed by an FDA inspector during the course of an inspection. The investigator's observations are subject to review and response by the Company and are further reviewed by other FDA personnel before the FDA makes a decision whether it believes the Company complies with applicable law and regulations.

This is an unusual case. The safety of the products manufactured by Utah Medical has never been at issue.

Even though product safety is a non-issue, the relief originally sought by the United States was to stop Utah Medical's products from entering commerce because of alleged persistent deficiencies of the Utah Medical in complying with the applicable quality system regulations (21 CFR § 820), and asserting that a failure to comply by definition produced an "adulterated" product and subjected the product and the persons responsible for the product to "regulatory action." In short, the United States asked that Utah Medical be ordered to stop the sale of product until Utah Medical complies with the regulation 21 CFR § 820 "*and in a manner that has been found acceptable to FDA*." (*See* Complaint, (emphasis added) ¶¶ IA and IB at 10.)

During the extended process carried on by the parties and by the Court in passing on motions and during the pretrial conference, and during the trial itself, the United States on the record softened the relief that it sought to simple regulatory compliance, and abandoned the more draconian relief of stopping sales of product defined as adulterated.

The relief early sought by the United States assumed that compliance with the regulations "and in a manner satisfactory to the FDA" are the same. But Utah Medical has asserted full compliance with the regulations and insists that the FDA misreads its own regulations.

The specific questions before the court, as set forth in the Pretrial Order, are three:

Issue No. 1(a): Whether Utah Medical has properly validated its extrusion and injection molding processes.

Issue No. 1(b): Whether Utah Medical has properly validated the software programs used as part of production or the quality system.

Issue No. 2: Whether Utah Medical properly processes complaints with regard to lookbacks and failure codes.

ANALYSIS

According to Mr. Cornwell, Utah Medical was originally founded in 1978 and went public in 1983. The QSR was adopted October 7, 1996 with an effective date of June 1, 1997.[5]

The regulations are characterized by the United States as general and flexible so as to cover a broad spectrum of products and activities, and that the regulations place a great deal of responsibility on a manufacturer to adopt and document internal practices and procedures which ensure the safety of the product. That general characterization is acquiesced in by Utah Medical.

For the most part, the substantive issues relate to the word "validation" as used in the regulations, the manner in which practices and procedures may be "validated," and whether the practices and procedures of the Utah Medical have been "validated" as required by the

[5] *See* 61 Fed. Reg. 52602-01, 52654, 1996 WL 565309 (Oct. 7, 1996).

regulations.

The United States asserts that the best source of validation information as to "current good manufacturing practice" is found in two publications: (1) *The Quality System Compendium*, (Assoc. for the Advancement of Medical Instrumentation, 1998) (Pl.'s Exh. 47); and (2) *Quality Management Systems - Process Validation Guidance*, 2d. ed. (The Global Harmonization Task Force, January 2004) (Pl.'s Exh. 99), and assert that such have been incorporated by the regulations. The regulations were effective in 1997. They do not expressly incorporate any industry publication, nor have they been amended to expressly include "future practices" which may be of benefit. Of course, it is fundamental that the regulations state the applicable law.

Medical device manufacturing is a heavily regulated industry, and rightfully so.

The applicable statute empowering the Secretary to promulgate regulations is found at 21 U.S.C. § 360j(f)(1)(A) and (B), and provides as follows:

> (A) The Secretary may, in accordance with subparagraph (B), *prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture,* pre-production design validation (including a process to access the performance of a device but not including an evaluation of the safety or effectiveness *of a device*), packing, storage, and installation of a device *conform to current good manufacturing practice, as prescribed in such regulations*, to assure that the device will be safe and effective and otherwise in compliance with this chapter.
> (B) Before the Secretary may promulgate any regulation under subparagraph (A) he shall–
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> > (i) afford the advisory committee established under paragraph (3) an opportunity to submit recommendations to him with respect to the regulation proposed to be promulgated;
> > (ii) afford opportunity for an oral hearing; and
> > (iii) ensure that such regulation conforms, to the extend practicable, with internationally recognized standards defining quality systems, or parts of the standards, for medical devices.
> > * * * *

21 U.S.C. § 360j(f)(1)(A)(B) (1999). (Emphasis added.)

Pursuant thereto, regulations were effective June 1, 1997 and are found at 21 C.F.R. Part 820 (2004). The United States asserts that Utah Medical has failed to comply with 21 C.F.R. §§ 820.75(a), 820.75(b), 820.70(i), 820.250(b), 820.100(a)(1), 820.90(a), 820.198(a), 820.70(a), 820.80(c) and 820.80(e) (2004). Utah Medical asserts full compliance.

Definitions found at 21 C.F.R. § 820.3(z) state:

> (z) *Validation* means confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.
>
> (1) *Process validation* means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

21 C.F.R. § 820.75 reads:

> **§ 820.75 Process validation.**
>
> (a) Where the results of a process cannot be fully verified by subsequent inspection and test, *the process shall be validated with a high degree of assurance and approved according to established procedures*. The validation activities and results, including the date and signature of the individual(s) approving the validation and where appropriate the major equipment validated, shall be documented.
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> (b) Each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met.
>
> (1) Each manufacturer shall ensure that validated processes are performed by qualified individual(s).
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> (2) For validated processes, the monitoring and control methods and data, the date performed, and, where appropriate, the individual(s) performing the process or the major equipment used shall be documented.
>
> (c) When changes or process deviations occur, the manufacturer shall review and evaluate the process and perform revalidation where appropriate. These activities shall be documented. (Emphasis added.)

21 C.F.R. § 820.70(i) reads in pertinent part as follows:

> (i) *Automated processes*. When computers or automated data processing systems

> are used as part of production or the quality system, the manufacturer shall *validate* computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented. (Emphasis added.)

21 C.F.R. § 820.198 reads in pertinent part as follows:

> **§ 820.198 Complaint files.**
> (a) Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:
> (1) All complaints are processed in a uniform and timely manner. . . .

21 C.F.R. § 820.250 states as follows:

> **§ 820.250 Statistical techniques.**
> (a) Where appropriate, each manufacturer shall establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics.
> (b) Sampling plans, when used, shall be written and based on a valid statistical rationale. Each manufacturer shall establish and maintain procedures to ensure that sampling methods are adequate for their intended use and to ensure that when changes occur the sampling plans are reviewed. These activities shall be documented.

As this matter progressed, it became clear to the court that the question is not whether the Utah Medical in times past fully and technically complied with the regulations, but whether Utah Medical is currently in compliance.

Past activities of the parties are of some help in discerning the need, if any, for a court order as sought by the United States.

Since about 2001, there has been an ongoing interplay between the agency and Utah Medical through the FDA oversight process of inspections, written observations by inspectors, responses by Utah Medical, review by District Directors and others, disagreements with the observations, purported "corrective actions" by the Utah Medical, and the gathering and

furnishing of documents of various kinds to satisfy the FDA.

1. Utah Medical Adequately Validates its Manufacturing Process in accordance with the Quality System Regulations.

The United States' proffered experts testified that Utah Medical has not properly validated its extrusion or injection molding processes used to make plastic parts. The United States generally contends that there is insufficient documentation demonstrating: (a) a proper installation of the extrusion and injection molding equipment; (b) proper calibration of the extrusion and injection molding equipment; (c) proper establishment of process parameters for the extrusion and injection molding processes; (d) adequate monitoring of critical dimensions of products manufactured through the extrusion and injection molding processes; (e) adequate inspection and testing of products manufactured through the extrusion and injection molding process; and (f) "edge of failure" testing of its processing parameters. The United States' experts stated that, according to industry standards, "process validation requires three separate elements known as "installation qualification" (IQ), "operational qualification" (OQ), and "performance qualification" (PQ). But at trial, the United States' experts repeatedly testified that it was the Company who must establish and maintain a quality system that is appropriate for the specific medical devices designed or manufactured.[6]

First, as to installation validation, the machines used for injection and extrusion have been in place and producing product for many years.

Currently, manuals and drawings contained therein are on hand and available. In an effort to "validate" "installation" which took place years earlier, Utah Medical used its own

[6]21 C.F.R. 820.5 reads "[e]ach manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device(s) designed or manufactured, and that meets the requirements of this part."

engineers to go through a comparable testing process in 2004.

Though done years after actual installation, the in-house engineers checked out the installation over a period of months and documented what they did over a period of months. They determined that the machines were properly installed. To the Court, that seems perfectly adequate. It verifies currently the validity of what was done at installation. The movie can't be run backwards, nor the clock turned back. The current effort by Utah Medical, of course, is to ensure product safety by doing now and providing documentation of a comparable "installation" series of tests. Such complies with the regulation. So much for installation.

Utah Medical establishes its processing parameters in part during the design phase of its manufacturing process. *See* 21 C.F.R. 820.75(b). Utah Medical identifies critical dimensions for all of its extruded and injection molded products. Utah Medical calibrates its extrusion and injection molding equipment on a regular, periodic basis, following established, documented procedures. This calibration work is done periodically and regularly by outside vendors. Utah Medical employs a statistical process control procedure to monitor and control its extrusion and injection molding process, by which samples of component parts are inspected at regular intervals. Process parameters are established and followed, and inspection occurs. All steps are documented.

The United States also asserts that process validation is deficient due to an absence of "edge of failure" testing, or in other words, testing of at what point process parameters do not work. But each product has design and operational specifications; each has an operation sheet provided to machine operators with specification limits presented by the engineer; each has a history sheet which is kept; each has a specification sheet, and designated temperature ranges,

speed of a particular run, pressure, as well as the stated directions from suppliers of raw material for the use of raw material. Measurement by laser beam is instantly available on tubing. There is a plethora of documentation as to what is to be done and what is done each step of the way. "Edge of failure" testing to demonstrate what does not work makes no sense when engineers have specified what does work and what has worked over years of operation.

Moreover, assembled products are all visually inspected, often more than once prior to shipment to customers.

For the reasons stated above, the Court finds that Utah Medical has adequately validated its manufacturing processes in accordance with the Quality System Regulations.

2. Utah Medical Adequately Validates its Software in compliance with the Quality System Regulations.

The United States expert Daniel Olivier testified that Utah Medical has not validated software that it uses in production or its quality system in accordance with "industry standards." He suggested that Utah Medical was deficient in three ways: (a) failure to document an intended use for each software program requiring validation; (b) improper sequencing of test protocols and test reports, in that certain test protocols were finalized after the relevant test reports; and (c) the existence of a so-called "Y2K" problem.

Utah Medical presented substantial testimony and documentary evidence that it validates its software for the software's intended use. Date discrepancies of a trivial nature and Y2K matters were easily explained by later drafts, interlineations, or typographical errors unrelated to validation. The undisputed hands-on testimony confirmed that the intended use of the software used by Utah Medical is adequately documented and the software is tested properly.

3. Utah Medical Has a Uniform Complaint Handling Process in compliance with the Quality System Regulations.

The United States experts testified that: (a) Utah Medical does not assign "failure codes" to complaints in a uniform manner; and (b) Utah Medical's "look-back" analyses are not performed in a uniform manner. A "look-back" refers to the company's investigation of new complaints by looking back at prior complaint files that may be relevant to the current issue or complaint under review. A "failure code" is a code assigned by a Utah Medical employee to generally characterize the issue associated with each complaint. Once again, the United States asserts that this process does not comport with "industry standards."

Utah Medical has established uniform procedures for implementing corrective and preventive action in accordance with 21 C.F.R. § 820.100(a). The company employs a detailed and uniform procedure that it follows for receiving, reviewing, and evaluating complaints. Utah Medical has documented its complaint-handling procedure. (*See* Def.'s Exh. 318.) Utah Medical uses "failure codes" merely as an internal general trending tool. The Company groups complaints not by failure codes, but by a corrective action number, allowing people to review similar complaints, if any, according to the corrective action number. These complaints are initially the responsibility of one individual, Russell Pope. The company holds regular weekly meetings to discuss complaints. In addition, complaints are periodically reviewed by the Chief Executive Officer, Kevin Cornwell.

Utah Medical is in compliance with Quality System Regulations as to complaint handling under 21 C.F.R. § 820.90(a) and § 820.198(a).

The question here is whether the processes and procedures used by Utah Medical to

currently produce product comply with the applicable regulations. The answer is yes, they do. That is a different question than whether Utah Medical has historically, from 2001, always been in full technical compliance.

It seems to me that a recurring problem in this extended and in some instances "nit-picking" case is a failure of the regulator and the regulated to communicate. It appears to me they have often talked past each other and, while using the same words, have meant entirely different things. This seems to be a common characteristic of both, arising in part because of the general nature of the regulations themselves, which have the virtue of generality and the vice of imprecision. This endemic problem is perhaps augmented by decision-makers who themselves rely too much on inspectors' reports without taking a fresh look themselves at ongoing changes made by Utah Medical in response to questions raised.

Each of the parties, of course, has a point. Utah Medical in times past may have lacked documentation of the particular kinds they now say are readily available, such as injection molding manuals and drawings. Utah Medical may well have applied an incorrect electronic label to a complaint, but the complaint process itself was both uniform and effective. Even counsel for the United States acknowledged that if computer labels were not used at all, the complaint handling process would be satisfactory.

The court has been impressed, for the most part, by the diligence of agency oversight. The court has been impressed as well by the Utah Medical's design of product, its record-keeping of each step along the way, the acceptance in the market of its products, the Company's uniform processing of complaints, and the manner in which change is made in practice and procedure as a result of complaint handling.

As this case progressed, the court wondered how it had evolved into a litigation with hundreds of exhibits, endless depositions, and high-cost "experts."

The common mission of the manufacturer and the regulating agency is a safe product and the adoption of manufacturing processes which ensure safety.

Product safety is not an issue in this case. Processes and procedures are. "Validation" is the key word, and has often been noted, "many roads lead to Rome."

The fact that the road chosen by Utah Medical may be different in degree than that thought to be appropriate by a regulator, does not mean that it is wrong, or in violation of the regulations. The regulations talk of current manufacturing practice. "Current good manufacturing practice (CGMP) requirements are set forth in this quality system regulations." 21 C.F.R. § 820.1(a).

The regulations were promulgated in 1997 with no express incorporation of industry standards. The suggestions found in *The Quality System Compendium* and *Quality Management Systems - Process Validation Guidance* may be of some value as evidence of some standards suitable for some manufacturers, but in no sense are specifically embraced by the regulations, nor have changes been made in the regulations to incorporate them. The statute, of course, talks of "current good manufacturing practice, as prescribed in such regulations." 21 U.S.C. § 360j(f)(1)(A)(B) (1999).

Without a doubt, the United States captured Utah Medical's attention in the past, and whatever modest deviations from *regulations* may have occurred in times past no longer exist at present. It makes no sense for the court to order Utah Medical to do something they are already doing.

Utah Medical's pending motions are mooted by this Opinion.

Petition DENIED, and case DISMISSED.

SO ORDERED.

Let judgment be entered accordingly.

DATED this 21 day of October, 2005.

BY THE COURT:

Bruce S. Jenkins
United States Senior District Judge